IAP12 Rec'd PCT/PTO 01 MAY 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lu	idmerer, Steve W. et al.	•	
Filed:	·	Art Unit: Examiner:	

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

EXPRESS MAIL CERTIFICATE DATE OF DEPOSIT MAY 1,2006 EXPRESS MAIL NO. EV 32198923005 I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE" ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, MAILED BY UNDER COMMISSIONER COMMISSIONER FOR PATENTS COMMISSIONER FO	I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below. MERCK & CO., INC.
DATE May 1,2006	ByDate

IAP12 Rec'd PCT/P

RELATED APPLICATION

MERCK CASE

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	U. S. SERIAL NUMBER	FILING DATE	MERCK CASE				
If this	is inconvenient, additional copies will be submitted upon reques	t.					
6.	In accordance with 37 C.F.R. 1.97, (check one)						
✓ th	ne attached information is filed within three months of the filing da	te of the captioned case.					
	ne attached information is filed more than three months after the following the merits.	iling date but prior to the m	ailing of a first				
1 1	ne attached information is filed before the mailing of a first Office a xamination under §1.114.	action after the filing of a re	quest for continued				
- C	ne attached information is being filed more than three months after of the section on the merits, but before the mailing date of a Final Antherwise closes prosecution in the application. The enclosed aut account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).	action, Notice of Allowance, horization is therefore give	, or an action that				
fr fr	ach item of information contained in this Information Disclosure Som a foreign patent office in a counterpart foreign application not statement.		•				
fr	each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.						
fo a	no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.						
		Respectfully submitted,					
			•				

Sh gr By: Sheldon O. Heber Attorney For Applicant(s) Reg. No. 38,179 MERCK & CO., INC. Patent Dept., RY60-30 P.O. Box 2000 Rahway, N.J. 07065-0907 (732)594-<u>1958</u> Date: May / 2006

ի արգագրության անականության 161 ՈՈՐան, Հում և Ունել
SUBSTITUTE for PTO/SB/08A (07-05), Information Disclosure Statement by Applicant
Patent and Trademark Office: W.S. DEPARTMENT OF COMMERCE

	Substitute for form 1449A/PTO			COMPLETE IF KNOWN 7				
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number 2	ec'd PCT/PTO 01 MAY 2006			
				Filing Date				
)	STATEWIENT DI	Ar	PLICANI	First Named Inventor	Ludmerer, Steven W. et al.			
			,	Group Art Unit				
	(use as many sheets	asn	necessary)	Examiner Name				
Sheet	1	of	. 3	Attorney Docket Number	21564YP			

		<u>U</u>	.S. PA	ATENT DOCUMENTS	
Examiner Cite Initials* No.		U.S. Patent Document Number	Kind Code known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		6,630,343 B1		Bartenschlager, R.	10/07/2003
		6,383,768 B1		De Francesco, R. et al.	05/07/2002
	•				-
1				•	
	۸۵۹				
			6		
			 		
· 10					
	_				
			 		
			<u> </u>		
			:		

		, .	FOREI	GN PATENT	DOCUMENTS	
Examiner Cite Initials* No.		Office	Foreign Patent Documen Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		wo	02/059321 A2		Istituto di Ricerche di Biologia Molecolare P. Angeletti S.p.A.	08/01/2002
		wo	02/052015 A2		Boehringer Ingelheim (Canada) Ltd.	07/04/2002
		wo	02/038793 A3		Anadys Pharmaceuticals, Inc.	05/16/2002
	,	wo	01/089364 A3		Washington University	11/29/2001

Examiner Signature Date Considered

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

	, 1			Appust of fine the Lange 101,000C. OMD 0Cf1 0991 SUBSTITUTE for PTO/SB/08A (07-05), Information Disclosure Statement by Applicant Patent and Trademark Office; US DEFARTMENT OF COMMERCE			
	Substitute for form 1449B/PTO INFORMATION	DIS	CLOSURE		COMPLETE IF KNOWN COMPLETE IF KNOWN COMPLETE OF		
	STATEMENT BY	AT	DI ICANT	Filing Date			
i.	SIAIENIENI DI	Ar	TLICANI	First Named Inventor	Ludmerer, Steven W. et al.		
	(Group Art Unit			
	(use as many sheets	asr	necessary)	Examiner Name			
Sheet	2	of	3	Attorney Docket Number	21564YP		

		NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bartenschlager, R. "Hepatitis C virus replicons: potential role for drug development", Nature Reviews, 2002, Vol. 1, pp. 911-916
		Bartenschlager, R. et al. "Nonstructural Protein 3 of the Hepatitis C Virus Encodes a Serine-Type Proteinase Required for Cleavage at the NS3/4 adn NS4/5 Junctions", Journal of Virology, 1993, Vol. 67, pp. 3835-3844
		Behrens, S. et al. "Identification and properties of the RNA-dependent RNA polymerase of hepatitis C virus", The EMBO Journal, 1996, Vol. 15, pp. 12-22
		Blight, K. et al. "Efficient Initiation of HCV RNA Replication in Cell Culture", Science, 2000, Vol. 290, pp. 1972-1974
		Carroll, S. et al. "Inhibition of Hepatitis C Virus RNA Replication by 2'-Modified Nucleoside Analogs", The Journal of Biological Chemistry", 2003, Vol. 278, pp. 11979-11984
		Choo, Q. et al. "Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome", Sciene, 1989, Vol. 244, pp. 359-362
		Farci, P. et al. "Clinical Significance of Hepatitis C Virus Genotypes and Quasispecies", Seminars in Liver Disease", 2000, Vol. 20, pp. 103-126
		Grakoui, A. et al. "A second hepatitis C virus-encoded proteinase", Proc. Natl. Acad. Sci. USA, 1993, Vol. 90, pp. 10583-10587
		Grakoui, A. et al. "Expression and Identification of Hepatitis C Virus Polyprotein Cleavage Products", Journal of Virology, 1993, Vol. 67, pp. 1385-1395
		Grobler, J. et al. "Identification of Key Determinant of Hepatitis C Virus Cell Culture Adaptation in Domain II of NS3 Helicase", The Journal of Biological Chemistry, 2003, Vol. 278, pp. 16741-16746
		Hijikata, M. et al. Proteolytic processing and membrane association of putative nonstructural proteins of hepatitis C virus", Proc. Natl. Acad. Sci. USA, 1993, Vol. 90, pp. 10773-10777
		Ikeda, M. et al. "Selectable Subgenomic and Genome-Length Dicistronic RNAs Derived from an Infectious Molecular Cone of the HCV-N Strain of Hepatitis C Virus Replicate Efficiently in Cultured Huh7 Cells", Journal of Virology, 2002, Vol. 76, pp. 2997-3006
		Krieger, N. et al. "Enhancement of Hepatitis C Virus RNA Replication by Cell Culture-Adaptive Mutations", Journal of Virology, 2001, Vol. 75. pp. 4614-4624
		Kuo, G. et al. "An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis", Science, 1989, Vol. 244, pp. 362-364
		Lohmann, V. et al. "Biochemical and Kinetic Analyses of NS5B RNA-Dependent RNA Polymerase of the Hepatitis C Virus", Virology, 1998, Vol. 249, pp. 108-118

Examiner Signature	Date Considered		
		<u></u>	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SUBSTITUTE for	PTO/SB/08A (07-05), Information Disclosure Statement by Applicant Patent and Trademark Office; U.S. DEPARTMENT OF COMMENCE	
C	OMPLETE IF KNOWN U 1 2 1 1 0 7	
lication Nambel 2 R	ec'd PCT/PTO 01 MAY 2006	
ng Date		

Substitute for form 1449B/PTO			COMPLETE IF KNOWN U 1 9 / 1 O X		
ľ	NFORMATION	DIS	CLOSURE	Application Namber 2	ec'd PCT/PTO 01 MAY 2006
C	TO A TOTAL MODERNITY TO NA	A TO	DI ICANIT	Filing Date	
3	STATEMENT BY APPLICANT			First Named Inventor	Ludmerer, Steven W. et al.
	,		•	Group Art Unit	
	(use as many sheets	as n	ecessary)	Examiner Name	
Sheet	3	of	3	Attorney Docket Number	21564YP

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS
Initials*	No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Lohmann, V. et al. "Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation" Journal of Virology, 2001, Vol. 75, pp. 1437-1449
		Lohmann, V. et al. "Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line", Science, 1999, Vol. 285, pp. 110-113
		Lohmann, V. et al. "Viral and Cellular Determinants of Hepatitis C Virus RNA Replication in Cell Culture", Journal of Virology, 2003, Vol. 77, pp. 2007-3019
		Love, R. et al. "Crystallographic Identification of a Noncompetitive Inhibitor Binding Site on the Hepatitis C Virus NS5B RNA Polymerase Enzyme", Journal of Virology, 2003, Vol. 77, pp. 7575-7581
		Mizushima, H. et al. "Analysis of N-Terminal Processing of Hepatitis C Virus Nonstructural Protein 2", Journal of Virology, 1994, Vol. 68, pp. 2731-2734
		Murray, E. et al. "Persistent Replication of Hepatitis C Virus Replicons Expressing the B-Lactamase Reporter in Subpopulations of Highly Permissive Huh7 Cells", Journal of Virology, 2003, Vol. 77, pp. 2928-2935
		Pawlotsky, J. et al. "Hepatitis C virus (HCV) NS5A protein; role in HCV replication and resistance to interferon α", Journal of Viral Hepatitis", 1999, Vol. 6, pp. 47-48
		Pietschmann, T. et al. "Characterization of Cell Lines Carrying Self-Replicating Hepatitis C Virus RNAs", Journal of Virology, 2001, Vol. 75, pp. 1252-1264
		Takamizawa, A. et al. "Structure and Organization of the Hepatitis C Virus Genome Isolated from Human Cariers", Journal of Virology, 1991, Vol. 65, pp. 1105-1113
		Tomei, L. et al. "Mechanism of Action and Antiviral Activity of Benzimidazole-Based Allosteric Inhibitors of the Hepatitis C Virus RNA-Dependent RNA Polymerase", 2003, Vol. 77, pp. 13225-13231
		Tomei, L. et al. "NS3 Is a Serine Protease Required for Processing of Hepatitis C Virus Polyprotein", Journa of Virology, 1993, Vol. 67, pp. 4017-4026
		Vrolijk, J. et al. "A replicon-based bioassay for the measurement of interferons in patients with chronic hepatitis C", Journal of Virological Methods, 2003, Vol. 110, pp. 201-209
		Wang, M. et al. "Non-nucleoside Analogue Inhibitors Bind to an Allosteric Site on HCV NS5B Polymerase" The Journal of Biological Chemistry, 2003, Vol. 278, pp. 9489-9495

Examiner Signature		Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.